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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,459	08/14/2003	David M. Rapoport	50124/01301	2146

7590 12/06/2004

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EXAMINER
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NATNITHITHADHA, NAVIN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,459

Applicant(s)

RAPOPORT ET AL.

Examiner

Navin Natnithithadha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 06212004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-4, 6-18, and 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthon-Jones et al, US 6,363,933 B1, in view of Ruton et al, US 6,409,676 B2.

In regards to claims 1 and 15, Berthon-Jones teaches a positive airway pressure system and method for treatment of sleep apnea (see figs. 1 and 2), comprising: a motor-servo unit 40 for supplying pressurized airflow to a patient (see col. 7, lines 60-64); a sensor 48 to measure data corresponding to the patient's breathing patterns (see

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col. 9, lines 24-26); and a controller 26 analyzes the breathing patterns to adjust the applied pressure (see col. 8, lines 35-42, and col. 9, lines 25-35). Berthon-Jones does not teach the controller 62 analyzes the breathing patterns to determine whether the breathing patterns are indicative of the following patient's states: a regular breathing state, a sleep disorder breathing state, a REM breathing sleep state, and a troubled wakefulness state. However, Ruton teaches a process for determining the states of respiratory phases of sleep comprising "*at least*" one state of normal respiration, a state of apnea, and a state of hypopnea (see col. 2, lines 58-63), which also suggests other states may be included. Therefore, Ruton teaches or suggests analyzing breathing patterns to determine the different patient states as claimed. It would be obvious for one of ordinary skill in the art at the time the invention was made to include Ruton's process into Berthon-Jones system and method in order to establish a correct diagnosis of respiratory disorders and to determine and initiate adequate and effective treatment (see Ruton, col. 2, lines 15-18).

As to claims 2, 11-14, 16, and 25-28, Berthon-Jones teaches the controller 26 controls the generator 14 to increase and decrease the pressure (see col. 8, lines 35-40). Berthon-Jones does not teach the controller 26 controls the generator to adjust the airflow pressure to the patient based on the patient's state. However, Ruton teaches or suggests analyzing breathing patterns to determine the different patient states as claimed. Berthon-Jones system and method would be capable of controlling generator 40 to increase, decrease, or maintain the pressure to the patient based on the analysis of Ruton's process. Therefore, it would be obvious for one of ordinary skill in

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the art at the time the invention was made to include Ruton's process into Berthon-Jones system and method in order to establish a correct diagnosis of respiratory disorders and to determine and initiate adequate and effective treatment (see Ruton, col. 2, lines 15-18).

As to claims 3, 4, 17, and 18, Berthon-Jones teaches measuring an airflow rate and applied pressure (see col. 9, lines 24-27).

As to claims 6 and 20, Berthon-Jones teaches the controller 26 monitors and adjusts the airflow and the pressure supplied by the generator 40 until the system (see col. 7, lines 60-64).

As to claims 7-9 and 21-23, Berthon-Jones teaches a mask 30, tube 32, and exhaust 42 (see fig. 2).

As to claims 10 and 24, Berthon-Jones does not teach the claimed subject matter. However, Ruton teaches means 23 for determining the patient's state by applying fuzzy logic rules to the analyzed breathing patterns (see col. 6, lines 57-67). Ruton also teaches database 57 for storing the fuzzy variables involved in determining the patient's state (see col. 7, line 56). It would be obvious for one of ordinary skill in the art at the time the invention was made to include Ruton's process into Berthon-Jones system and method in order to establish a correct diagnosis of respiratory disorders and to determine and initiate adequate and effective treatment (see Ruton, col. 2, lines 15-18).

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2. Claims 5 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthon-Jones et al, US 6,363,933 B1, in view of Ruton et al, US 6,409,676 B2, as applied to claims 1 and 15 above, and further in view of Karakasoglu et al, US 6,171,258 B1.

As to claims 5 and 19, Berthon-Jones and Ruton do not teach the subject matter as claimed. However, Karakasoglu teaches obtaining data corresponding to EEG, heart rate and blood pressure (see col. 5, lines 51-56) in order to detect events such as healthy breathing, hypopnea, and apnea (see col. 7, lines 6-14). It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Berthon-Jones and Ruton with that of Karakasoglu in order to properly determine sleep disorders.

### ***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (703) 305-2445. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

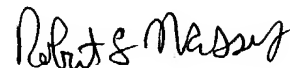
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Navin Natnithithadha  
Patent Examiner  
GAU 3736  
November 18, 2004



ROBERT L. NASSER  
PRIMARY EXAMINER